**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | |
|---|---|
| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456<br>Civil Action No. 01-12257-PBS<br>Subcategory Case No: 03-10643-PBS |
| THIS DOCUMENT RELATES TO:<br>*The City of New York, et al.*<br>*v.*<br>*Abbott Laboratories, et al.* | Judge Patti B. Saris |

**PLAINTIFFS' REPLY TO SCHERING CORPORATION'S, SCHERING-PLOUGH CORPORATION'S, AND WARRICK PHARMACEUTICALS CORPORATION'S RESPONSE TO PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF "UNDISPUTED" MATERIAL FACTS AS TO SCHERING CORPORATION, SCHERING-PLOUGH CORPORATION, AND WARRICK PHARMACEUTICALS CORPORATION AND STATEMENT OF ADDITIONAL UNDISPUTED MATERIAL FACTS**

Pursuant to Local Rule 56.1, Plaintiffs' submit this Reply to Schering Corporation ("Schering"), Schering-Plough Corporation ("Schering-Plough"), and Warrick Pharmaceuticals Corporation's ("Warrick") (collectively, the "Warrick Defendants" or "Schering/Warrick") Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to the Warrick Defendants in support of their Motion for Partial Summary Judgment.

## I. DEFENDANT SPECIFIC FACTS

**1.** The Schering/Warrick Drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Schering/Warrick's Published AWPs and DPs/WACs for these Drugs and NDCs. The exhibit specifically notes which NDCs are associated with package sizes that set the FUL.

Response: Disputed in part.
The Warrick Defendants acknowledge that Exhibit A sets forth the Warrick drugs at issue in this motion. The Warrick Defendants also acknowledge that Exhibit A lists AWPs and FULs and purports to provide Direct Prices and WACs for such drugs. The Warrick Defendants dispute that the listed values constitute Warrick's "AWPs" or "Published DPs/WACs" for such drugs. With respect to WACs, as set forth in General Response

No. 3 above, Warrick did not have WAC prices and did not report a WAC for the Subject Drugs to any pricing compendia. *See* Tab B, Deposition of Harvey Weintraub, Sept. 18-22, 2006 ("Weintraub Dep.") at 154-59. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id.*; *see also id.* at 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). None of the pricing compendia, First DataBank, Medispan or Red Book, ever reported a WAC for Warrick's drugs in their hard-copy publications. Because Warrick did not subscribe to First DataBank's electronic pricing service, Warrick was never aware, during the relevant time, that First DataBank was reporting Warrick's Direct Price at launch as a WAC. See *id*. at 154 & 387. Rather, Warrick only reviewed First DataBank's monthly Price Alerts, which First DataBank specified were its "official" pricing guides. See *id*. at 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product); *id*. at 150 (Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents); Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2. With respect to Direct Prices or DPs, at the launch of a product, Warrick generally set a direct price. *See* Weintraub Dep. at 153-54 & 353 (direct price was the "going-out price" that Warrick intended to get if it could); *id.* at 566 (direct price was the initial "going-out price" expected for the wholesale class of trade). Warrick typically sent letters at the launch of a product to customers, pricing compendia, and state Medicaid agencies, including New York, providing notice of the product's AWP and NDC number, and occasionally its direct price at launch. *See, e.g., id.* at 639 (testifying that Warrick's procedure when launching a new product was to notify First DataBank of the AWP and NDC numbers); Tab D, Letter from Harvey Weintraub to Beth Rader and Ed Edlestein dated Sept. 3, 1993 (announcing availability of 25 x 3 ml albuterol sulfate inhalation solution 0.083%, 59930-1500-08 and reporting AWP and direct price at launch); Tab E, Letter from Harvey J. Weintraub to Beth Rader dated Dec. 29, 1995 (announcing availability of albuterol USP inhalation aerosol (59930-1560-1) and refill (59930-1560-2) and reporting AWP); Tab F, Letter from Phyllis T. Sinoradzki, M.A.E. to Arnold Shapiro dated Dec. 30, 1995 (announcing availability of albuterol USP inhalation aerosol (59930-1560-1) and refill (59930-1560-2) and reporting AWP and direct price at launch for same). After launch, Warrick did not maintain a uniform direct price that was the same for each customer. *See* Weintraub Dep. at 153. For that reason, in a letter dated October 12, 1993, Harvey Weintraub asked First DataBank to "[p]lease delete direct price listings from your publication or database." *Id.*; *see* also Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Mr. Weintraub confirmed that First DataBank complied with his request by reviewing the First DataBank publication to ensure no Warrick Direct Prices were included. See Weintraub Dep. at 153-54. As noted below, Warrick also did not have ultimate control over the AWPs published for its products by the national pricing compendia. *See infra* Responses to ¶ 9.

**PLAINTIFFS' REPLY TO STATEMENT #1:**

Warrick has admitted that it did publish WAC for the subject drugs, consistent with its Direct Price. Toward this end, Warrick adopted a policy requiring all publications of AWP and WAC pricing to third parties (other than to customers in the context of negotiating selling prices) first be reviewed with Harvey Weintraub. *See*, Exhibit A. Exhibit A is a memorandum from then-president of Warrick, Ray Kapur enunciating this policy on September 8, 1998, with the stated purpose of ensuring "uniformity in approach and the consistent application of the correct and appropriate criteria" to such price reports. Weintraub testified that the criterion he found to be "correct and appropriate" to this purpose was that the WAC price quoted be "consistent with our direct price..." *See* Warrick Pharmaceuticals Corp. 30(b)6) (Harvey Weintraub) 9/20/06 Deposition Transcript (Exhibit B) at 561:5-562:9 (hereinafter "Warrick 30(b)(6) (Weintraub) 9/20/06 Dep. (Exhibit B)")

The record shows that when Weintraub personally published Warrick's WAC directly to a state Medicaid agency, he used a number that was precisely Warrick's Direct Price. One example of this is Weintraub's WAC report to Maryland Medicaid. *See*, Exhibit C. Exhibit C is a form sent by the Maryland Medicaid agency to Warrick requesting (among other prices) WAC for the 17g albuterol inhaler. Weintraub acknowledges that he wrote in the prices shown as Wholesale Acquisition Cost, Direct Price, Distributor Price, and Average Wholesale Price. The first three prices for the Albuterol inhaler are identical. *See*, Warrick 30(b)(6) (Weintraub) 9/20/06 Dep. (Exhibit B) at 568:2-23. That Warrick published WAC to the pricing compendia (as well as directly to state Medicaid agencies) cannot seriously be said to be in dispute simply because it chose to call it something else. This is particularly true when Warrick picked other names to call its price to Wholesaler in the context of publications to state Medicaid agencies,

such as "Direct Wholesale." *See*, Exhibit D and Warrick 30(b)(6) (Weintraub) 9/20/06 Dep. (Exhibit B) at 564:7-565:13. Exhibit D is an example of a form letter which went out contemporaneously with the launch of the albuterol inhaler in 1995 to all the state Medicaid agencies. Its use of the term "Direct Wholesale" obscures any ostensible distinction between Warrick's "Direct Price" and its "Wholesale Acquisition Cost."

Warrick also admits that it has published WAC to First Databank for the sterile albuterol solutions in July of 2002. *See*, Exhibit E. This document shows "WAC" prices provided by Weintraub, who testified that he was providing WAC in response to FDB's "direct request." *See*, Warrick 30(b)(6) (Weintraub) 9/20/06 Dep. (Exhibit B) at 605:2-21. Although Warrick claims not to know why WAC was provided for these products at this time, Warrick has admitted that the June of 2002 it had announced the introduction of the sterile albuterol inhalation solutions and published their AWP prices to the pricing services, including FBD, as well as to the various state Medicaid agencies, directly. *See*, Exhibit F. Warrick acknowledges that WAC was being provided its new sterile solutions as a condition of listing those new sterile solutions in FDB's publications. *See*, Defendants' response to Statement No. 12. This is entirely consistent with Warrick's having, in 1993, published its Direct Prices to FDB to serve as WAC for purposes of supporting the products' listing in FDB's publications.

Warrick admits that it had access to all of the resources of Schering as a unit of Schering-Plough, and that its decision not to use any particular part of them in the prosecution of Warrick's business was deliberate. *See*, Warrick 30(b)(6) (Weintraub) 9/21/06 Dep. (Exhibit B) at 749:21-750:22. It is undisputed that Schering, and Warrick had it chosen to exercise it, had recourse to the electronic version of the FDB National Drug Data File. *See*, Exhibit G. And finally, Janice Brennan, the Schering employee whose job it was to interface with Medicaid

agencies and pricing services, clearly did so on behalf of Warrick, and indisputably had access to the electronic NDDF files showing that Warrick's WACs were being published electronically in spite of the fact that they were not published in the paper publication. *See,* Warrick 30(b)(6) (Weintraub) 9/20/06 Dep. (Exhibit B) at 583:5-13 and Exhibit G.

*See also* Reply Affidavit of Joanne M. Cicala, sworn to June 30, 2009 and submitted in further support of plaintiffs' motion for partial summary judgment at ¶2, which is incorporated herein.

The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**2.** The specific Schering/Warrick drugs at issue are the Albuterol .83 mg/ml solution, the Albuterol 90 MCG Inhaler and Isosorbide Mononitrate 60 MG Tablet.

Response: Disputed in part.
The Warrick Defendants acknowledge that the Warrick drugs at issue are the Albuterol .83 mg/ml solution, the Albuterol 90 MCG Inhaler and Isosorbide Mononitrate 60 MG Tablet. As set forth in General Response No. 1, the drugs identified in this paragraph are all generic, Warrick products. Accordingly, the Warrick Defendants dispute this alleged material fact to the extent it purports to relate to Schering.

**Plaintiffs' Reply:**

The parties agree that these are the drugs at issue. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**3.** Schering/Warrick has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. *See* Defendants Schering-Plough Corporation's, Schering Corporation's, and Warrick Pharmaceuticals Corporation's Answer to Plaintiffs' Revised First Amended Consolidated Complaint ("Schering/Warrick Answer") [Docket #4835] at ¶ 132; *see also Commonwealth of Mass. v. Mylan,* 2008 WL 5650859 *25 (D. Mass. Dec. 23, 2008).

RESPONSE: Disputed in part.

The Warrick Defendants acknowledge that Warrick has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. As set forth in General Response No. 1, the drugs identified in this paragraph are all generic, Warrick products. Accordingly, the Warrick Defendants dispute this allegedly material fact to the extent it purports to relate to Schering.

**Plaintiffs' Reply:**

Defendants do not actually dispute that Schering has entered into the rebate agreement, but merely that Schering is not involved with the subject drugs, therefore the Statement is undisputed.

**4.** Schering/Warrick was required as matter of law to familiarize itself with the legal requirements, standards and procedures of Medicaid reimbursement formulas. *Mylan*, 2008 WL 5650859 at *25.

The Warrick Defendants acknowledge only that, in *Commonwealth of Mass. v. Mylan*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008), this Court wrote "having entered into the rebate agreements, the defendants were required, as a matter of law, to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program." The Warrick Defendants deny this statement to the extent that it constitutes a legal conclusion and is unsupported by any factual citation to either the record or affidavits as required by Local Rule 56.1. In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its allegedly undisputed facts. Moreover, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-155. As set forth in General Response No. 1, the drugs identified in this paragraph are all generic, Warrick products. Accordingly, the Warrick Defendants dispute plaintiffs' alleged material fact to the extent it purports to relate to Schering.

**Plaintiffs' Reply:**

The parties agree that this Court has found that a defendant in this litigation is required, as a matter of law, to familiarize itself with the legal requirements, standards and procedures of Medicaid reimbursement formulas. No further reply is required.

**5.** Warrick knew that eligibility for reimbursement by Medicaid was an important issue for its customers. *See* Warrick Pharmaceuticals Corp. 30(b)6) (Harvey Weintraub) 9/18/06 Deposition Transcript (Exhibit B) at 173:5-9 (hereinafter "Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B)") ("In order to have our drugs purchased by the national accounts we certainly had to have our products reimbursed by – under the Medicaid programs.").

Response: Undisputed.
The Warrick Defendants acknowledge that Harvey Weintraub testified that "[i]n order to have our drugs purchased by the national accounts we certainly had to have our products reimbursed by - under the Medicaid programs." *See* Weintraub Dep. at 173. Mr. Weintraub's complete testimony continued "and so all we wanted to do was to be listed as a product for which they would reimburse. So we sent them out a letter saying, 'This is what our product is. Here's the NDC code. Please list it,' in essence." *Id*.

**Plaintiffs' Reply:**

Defendants' response, apart from acknowledging that the Statement is not in dispute, is irrelevant and disputed. No further reply is required.

**6.** Schering/Warrick was well aware of the importance of the Medicaid market and that many states use third-party pricing services for the pricing data used to establish reimbursement levels. *Id*. at 369: 7 – 371-23. In the Schering/Warrick "Action Plan" for the Albuterol Inhaler launch, the authors state at page 10 under the heading "MEDICAID, DUR AND PRICING SERVICES:" 1) One of the critical factors in the success of a generic product is to get reimbursement as quickly as possible. Third party reimbursers represent as much as 2/3 of an accounts utilization of a given product. It will be critical to achieve 100% reimbursement as quickly as possible. 2) Many states utilize third party pricing services to update their files for new additions as products become available for reimbursement on Medicaid. Letters should be prepared immediately for mailing the day of launch to all pricing services. *See*, Exhibit K (excerpts of Action Plan).

Response: Disputed in part.
The Warrick Defendants acknowledge only that Mr. Weintraub testified that it was important to Warrick's success that Warrick be listed and eligible for reimbursement by third-party payers including Medicaid. See Weintraub Dep. at 369. The Warrick Defendants deny that Warrick knew "that many states use third-party pricing services for the pricing data used to establish reimbursement levels." The deposition testimony cited by plaintiffs does not support this statement. *See id*. at 370 ("We wanted to be listed on the program. How the reimbursing agents determine their reimbursement, whether it was on one price or another, I don't know.") In addition, Exhibit K is inadmissible because the document is not authenticated, and Mr. Weintraub testified that he is not familiar with it, and it appeared to be a Schering (and not a Warrick) document. *See id*. at 366-67 & 372. Warrick acknowledges that Harvey Weintraub testified he was aware that AWP was used in the pharmaceutical industry as a sticker price, a point of reference from which negotiations between a third-party payor and the account it was servicing were started.

*See id*. at 135. Mr. Weintraub further testified that there were thousands of such third-party payors, including HMOs, insurance companies, and government agencies. *See id*. at 137. Mr. Weintraub also testified that no one at Warrick attempted to keep track of the specific reimbursement methods of these thousands of reimbursement plans and formulas, and that reimbursement "was not [their] focus" but, rather, their focus was "[p]rice, service, continuity of supply, [and] meeting the competition." *See id*. at 137 & 173-75 (Mr. Weintraub testified that Warrick did not know the specifics of each state's Medicaid reimbursement formula, did not know whether they all reimbursed in the same manner with the same formula at the same time, did not keep track of what the formulas were or how they changed from time to time, and did not consider that relevant to the business of selling Warrick generic drugs.). As set forth in General Response No. 1, the drugs identified in this paragraph are all generic, Warrick products. Accordingly, the Warrick Defendants dispute this allegedly material fact to the extent it purports to relate to Schering.

**Plaintiffs' Reply:**

Exhibit K to Plaintiff's Rule 56.1 Statement shows Schering's direct involvement in the business of Warrick (selling Schering generic products) and the importance to Schering/Warrick of Medicaid reimbursements to its market strategy. Defendants' response does not dispute the Statement, other than to attempt to characterize Warrick's acknowledged interest in Medicaid reimbursement as being outside of its "focus." Defendants' response, apart from its acknowledgment of the importance to Warrick of Medicaid reimbursement, is irrelevant and disputed. No further reply is required.

**Warrick Set and Reported Its AWPs and DPs**

**7.** Warrick reported an AWP for its drugs to the pricing compendia. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 151:9-11; Warrick Pharmaceuticals Corp. 30(b)6) (Harvey Weintraub) 9/19/06 Deposition Transcript (Exhibit C) at 376:6-9 (hereinafter "Warrick 30(b)(6) (Weintraub) 9/19/06 Dep. (Exhibit C)"). *Mylan*, 2008 WL 5650859 at *7. Warrick 30(b)(6) (Weintraub) 9/22/06 Dep. (Exhibit D) at 893:24-894:4.

Response: Disputed as written.
As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. The Warrick Defendants acknowledge that Warrick typically suggested an AWP at launch. To the extent that plaintiffs intend to imply Warrick continued to report AWPs periodically after launch, Warrick denies the implication. Tab

H, First DataBank Price History for Albuterol 90 MCG Inhaler (59930-1560-01) dated July 27, 2004, First DataBank Price History for Albuterol 90 MCG Inhaler Refill (59930-1560-02) dated July 27, 2004.

**Plaintiffs' Reply:**

Defendants' response does not dispute the Statement as written. No additional reply is required.

**8.** At all times, from 1997 to 2005, at the time of launch of a new product Warrick set an AWP for each of its drugs. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 166:17-24. *Mylan*, 2008 WL 5650859 at *7. Warrick has only one AWP for any Warrick product at any time. *See* Warrick Pharmaceuticals Corp. 30(b)6) (Harvey Weintraub) 9/22/06 Deposition Transcript (Exhibit D) at 852:21-23 (hereinafter "Warrick 30(b)(6) (Weintraub) 9/22/06 Dep. (Exhibit D)").

Response: Disputed in part.
As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. The Warrick Defendants acknowledge that Warrick typically suggested an AWP at launch and that Warrick has only one AWP for any Warrick product at any time.

**Plaintiffs' Reply:**

Defendants' response does not dispute the Statement as written. No further reply is required.

**9.** Warrick knew and controlled the AWPs for its drugs that were published by the national drug pricing compendia. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 154:9-16. First Databank would send requests to Warrick to verify the accuracy of the AWPs for its drugs. *See* Warrick 30(b)(6) (Weintraub) 9/22/06 Dep. (Exhibit D) at 843:7 – 844:3; 849:8-17.

Response: Disputed.
The Warrick Defendants deny that Warrick knew and controlled the AWPs for its drugs that were published by the national drug pricing compendia. The Warrick Defendants acknowledge only that, generally, the pricing compendia published the AWPs that Warrick had suggested at launch. The cited deposition testimony relates to a single episode in 1993 where Harvey Weintraub wrote to a pricing publication to request that the AWP of one package size of albuterol 0.083 % solution be lowered so as to make the

per unit AWP consistent with another package size, and where Mr. Weintraub later reviewed the publication to confirm that the change had been made. *See* Weintraub Dep. at 151-54. The Warrick Defendants deny that the lowering of AWP on one package size of the 0.083% solution in 1993 is a material fact for purposes of this litigation, as it is outside the relevant time period, and deny that this single episode demonstrates that Warrick "knew and controlled the AWPs for its drugs that were published by the national drug pricing compendia." The Warrick Defendants also deny that First DataBank would send requests to Warrick to verify the accuracy of the AWPs for its drugs. The Warrick Defendants acknowledge only that Harvey Weintraub testified that Warrick received requests to update AWPs. *See id*. at 843-44. Additional evidence suggests that First DataBank did not regularly send such requests. *See* Tab I, Deposition of Patricia Kay Morgan, Jan. 28, 2002 ("Morgan Dep.") at 19-22 (First DataBank had no policy to routinely request updated information from manufacturers); *see also* Weintraub Dep. at 639 (testifying that he did not recall any routine requests from First DataBank for information).

More generally, as this Court knows from its having presided over the McKesson case, no manufacturer "controlled" its AWPs. AWPs were published by the national pricing compendia, including specifically First DataBank, that unilaterally and over some manufacturers' objections, and to their detriment, raised AWPs for their products as a result of an agreement with McKesson and other wholesalers. The McKesson case makes plain that First DataBank did not function as the manufacturers' agent and the manufacturers did not "control" their AWPs or other published prices for that matter. *See, e.g., New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.D. 79 (D. Mass. 2007).

As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL.

**Plaintiffs' Reply:**

The parties agree that Warrick reported its AWP to the pricing compendia at launch and generally did not thereafter attempt to change its published AWP. The parties also agree that Warrick demonstrated the ability to alter its AWP which was published by FDB in the manner described in Defendants' response. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**10.** All published AWPs reflected what Warrick submitted to them. Warrick received written publications from First DataBank on either a bi-weekly or monthly basis and would

review them to confirm that First DataBank published the prices Warrick had submitted. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 154:9-16.

Response: Disputed in part.
The Warrick Defendants acknowledge that generally, the pricing compendia published the AWPs that Warrick had suggested at launch. Plaintiffs cite no record evidence, however, to show that "[a]ll published AWPs reflected what Warrick submitted to them." The Warrick Defendants acknowledge that Warrick periodically received written publications from First Databank but deny that Warrick would review each of those publications to confirm that First DataBank published the prices Warrick had submitted. The deposition cited refers to a single instance, in 1993, where Mr. Weintraub recalled reviewing a First DataBank publication to confirm that the published AWP was the one Warrick had suggested. *See* Weintraub Dep. at 153-54. The Warrick Defendants deny that this instance in 1993 in which Mr. Weintraub reviewed a First DataBank publication is a material fact for purposes of this litigation, as it is outside the relevant time period, and deny that this single episode demonstrates that Warrick generally "would review" First DataBank publications to confirm that the published AWPs were consistent with the AWPs Warrick had suggested. The McKesson litigation demonstrates, moreover, that published AWPs did not always reflect the prices manufacturers submitted to them. *See, e.g., New England Carpenters Health Benefits Fund v. First DataBank, Inc*., 244 F.R.D. 79 (D. Mass. 2007).

As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL.

**Plaintiffs' Reply:**

The parties agree that the pricing compendia published the prices that Warrick reported to them. Defendants offer no instance to the contrary. Furthermore, the parties agree that Warrick did consult the pricing publications to confirm that they published Warrick's prices as reported. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**11.** Warrick's Direct Price was synonymous with "Invoice Price" which was synonymous with WAC. Deposition of Harvey J. Weintraub dated 2/12/03 (Exhibit E) at 489:20-490:7; 592:7-17. 635:23-636:3; 708:15-20 (hereinafter "Weintraub 2/12/03 Dep. (Exhibit E)").

Response: Disputed in part.
The Warrick Defendants acknowledge only that Warrick, at the launch of a product, set a direct price, which Harvey Weintraub testified was "the price at which [Warrick]

invoiced an account." *See* Weintraub Dep. at 153-54, 353 (direct price was the "going-out price" that Warrick intended to get if it could), 566 (direct price was the initial "going-out price" expected for the wholesale class of trade). The Warrick Defendants dispute that Warrick's Direct Price is synonymous with WAC. As set forth in General Response No. 3 above, Warrick did not have WACs and did not report WACs for the Subject Drugs to any pricing compendia. *See id*. at 155-59. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id*. at 155-59 & 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). The Warrick Defendants understand WAC to be a list or invoice price used for all customers. None of the pricing compendia, First DataBank, Medispan or Red Book, ever reported a WAC for Warrick's drugs in their hard-copy publications. When Warrick realized that First DataBank was publishing Direct Prices for its drugs in 1993, it instructed First DataBank not to do so, and First DataBank ceased to publish Direct Prices (and never reported WACs) for Warrick's Subject Drugs in its hard-copy publication. *See* Weintraub Dep. at 153-55; Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Because Warrick did not subscribe to First DataBank's electronic pricing service, Warrick was never aware, during the relevant time, that First DataBank was reporting Warrick's Direct Price at launch as a WAC. *See* Weintraub Dep. at 154 & 387. Rather, Warrick only ever reviewed First DataBank's monthly Price Alerts, which First DataBank specified were its "official" pricing guides. *See* Weintraub Dep. at 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product) & 150 (Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents); Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2.

**Plaintiffs' Reply:**

See Plaintiff's Reply to Defendants' Response to Statement No. 1

**12.** Warrick did not report WACs for its drugs but reported DPs which Warrick knew FDB would publish as WACs. *See* Warrick Pharmaceuticals Corporation's Response to the Commonwealth of Massachusetts's Local Rule 56.1 Statement of Undisputed Material Facts Applicable to Warrick and Counterstatement of Additional Undisputed Material Facts, ("Response to Mass. 56.1") [Mass. Docket #475] (Exhibit F) at ¶11 (hereinafter "Warrick Resp. to Mass. SOF (Exhibit F)"), *Mylan*, 2008 WL 5650859 at *6. Warrick admits that it knew that Warrick's DPs were published as WACs, and on at least one occasion, provided its Direct Price to First Databank specifically and expressly to be published as its WAC, as a condition of having its products listed. *See* Warrick Resp. to Mass. SOF (Exhibit F) at footnote 1 on page 38 (describing a transaction between Harvey Weintraub on behalf of Warrick and Kay Morgan on behalf of First Databank in which Weintraub was informed that Warrick's Direct Price was considered by First Databank to be an appropriate proxy for WAC); *Mylan*, 2008 WL 5650859 at *17.

Response: Disputed in part.
The Warrick Defendants acknowledge only that they "did not report WACs for their drugs." With respect to the Direct Prices Warrick reported at launch, when Warrick discovered in 1993 that First DataBank was publishing those Direct Prices subsequent to launch, it instructed First DataBank to stop. *See* Weintraub Dep. at 153; *see also* Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id.*; *see also* Weintraub Dep. at 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). First DataBank complied and no longer published Direct Prices (and never published WACs) in its hard-copy publication. *See* Weintraub Dep. at 153-55. Accordingly, the Warrick Defendants deny that Warrick knew that First DataBank would publish the DPs submitted at launch as WACs. As set forth in General Response No. 3 above, Warrick did not have WACs and did not report WACs for the Subject Drugs to any pricing compendia. *See* Tab B, Weintraub Dep. at 155-59.

The Warrick Defendants deny that Warrick has ever admitted "that it knew that Warrick's DPs were published as WACs, and on at least one occasion, provided its Direct Price to First Databank specifically and expressly to be published as its WAC, as a condition of having its product listed." Warrick acknowledges that, in one isolated incident in July 2002, Warrick reported a WAC to pricing compendia when Kay Morgan of First DataBank directly asked Harvey Weintraub to provide WACs for its new sterile solutions as a condition of listing those new sterile solutions in its publication. *See* Tab J, Letter from Harvey Weintraub to Kay Morgan dated July 16, 2002. On that occasion, Mr. Weintraub informed First DataBank that Warrick "did not have WAC prices," but rather "that Warrick has a range of prices at which it sells its products at any given time." *See* Weintraub Dep. at 156. First DataBank informed Mr. Weintraub that "disclosing [Warrick's] highest WAC would be sufficient for [their] purposes" and in response, Warrick reported the highest prices for the albuterol sulfate inhalation solution. *Id.* Contrary to plaintiffs' statement, the letter in question makes no reference at all to Direct Price.

Further, notes taken by Kay Morgan, a First DataBank employee, of a subsequent conversation with Warrick confirm that First DataBank "used [its] own judgment" in setting Warrick's WAC. The notes state as follows:

> Called Harvey Winetraub [sic] and asked for WACs. Harvey stated that they do not have one priced [sic] for wholesalers. I asked which of prices attached should be used. After discussion Harvey will get back to me. Kay Morgan 4/15/2004
>
> * * *
>
> *Received message from Harvey Winetraub [sic] on 4/16 indicating they do not have WACs and I should use my own judgment.* Contracted wholesalers per attached. WAC equals system price.

Kay Morgan 4/21/04

*See* Tab K, Contested Privilege Dep. of James Breen, at 24–25 (emphasis added).

In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its alleged undisputed facts. Moreover, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-55.

**Plaintiffs' Reply:**

The salient aspects of Defendants' response are addressed above. See Plaintiff's Reply to Defendants' Response to Statement No. 1. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**13.** Warrick set AWP at launch and generally did not change it. *See* Warrick Resp. to Mass. SOF (Exhibit F) at 11. Warrick knew that FDB published its DPs in the hard copy version of FDB's pricing service. *Mylan*, 2008 WL 5650859 at *7. Warrick knew that FDB published its Direct Prices as WACs in the electronic form. *See* Warrick Resp. to Mass. SOF (Exhibit F) at 26.

Response: Disputed in part.
The Warrick Defendants acknowledge that Warrick typically suggested an AWP at launch and generally did not change it. As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. With respect to the Direct Prices Warrick reported at launch, when Warrick discovered in 1993 that First DataBank was publishing those Direct Prices subsequent to launch, it instructed them to stop. *See* Weintraub Dep. at 153; *see also* Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. First DataBank complied and no longer published Direct Prices (and never published WACs) in its hard-copy publication. *See* Weintraub Dep. at 153-55. The Warrick Defendants deny that Warrick knew that First DataBank published its Direct Prices as WACs in the electronic form. Warrick Pharmaceuticals Corporation's Response to the Commonwealth of Massachusetts's Local Rule 56.1 Statement of Undisputed Material Facts Applicable to Warrick and Counterstatement of Additional Undisputed Material Facts ("Warrick's Response to Mass. 56.1"), cited by plaintiffs as evidence to support such knowledge on the part Warrick, expressly denies such knowledge. *See* Tab L, Warrick's Response to Mass. 56.1, at Responses to ¶¶ 19, 21, 23-26, Counterstatement ¶ 10. As indicated in Warrick's Response to Mass. 56.1, none of the pricing compendia, First DataBank, Medispan or Red Book, ever reported a WAC for Warrick's drugs in their hard-copy publications. *Id.* at Responses to ¶¶ 19, 21, 23-24. When Warrick realized that First DataBank was publishing Direct Prices for its

drugs in 1993, it instructed First DataBank not to do so and First DataBank ceased to publish Direct Prices (and never reported WACs) for Warrick's Subject Drugs in its hard-copy publication. *See* Weintraub Dep. at 153-55; Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Warrick was never aware, during the relevant time, that First DataBank was reporting in its electronic pricing file the Direct Price that Warrick reported for its drugs at launch as a WAC, because Warrick did not subscribe to that service. *See* Weintraub Dep. at 154 & 387. Rather, Warrick only reviewed First DataBank's monthly Price Alerts, which First DataBank specified were its "official" pricing guides. *See id*. at 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product) & 150 (Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents); Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2.

In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its alleged undisputed facts. Moreover, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-55.

**Plaintiffs' Reply:**

The salient aspects of Defendants' response are addressed above. See Plaintiff's Reply to Defendants' Response to Statement No. 1. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**14.** Warrick produced at least one fax from First Databank to Warrick of FDB's 1999 National Drug Data File Product Update, listing Warrick's drugs and their WACs, demonstrating that Warrick was aware of the fact that FDB was publishing its Direct Prices as WAC. FDB Fax dated 3/2/99 (Exhibit G), Bates RGX 0190075-6; *Mylan*, 2008 WL 5650859 at *7.

Response: Disputed in part.
The Warrick Defendants acknowledge that Exhibit G to Plaintiffs' Local Rule 56.1 Statement as to the Warrick Defendants is a fax from First Databank to Warrick of FDB's 1999 National Drug File Data Product Update that was produced by Warrick. Warrick notes, however, that Exhibit G is inadmissible evidence. It is not addressed to anyone in particular, no one has authenticated it, and plaintiffs cannot show that anyone at Warrick ever saw it or reviewed it. Moreover, there is no evidence whether Warrick replied to the fax one way or the other. Indeed, Warrick's 30(b)(6) witness, Harvey Weintraub, testified that he never saw this document or any document like it. *See* Weintraub Dep. at 592-599. Furthermore, the document refers to WHLNET and not WAC. The term WAC

appears nowhere on the document and, for that reason alone, plaintiffs' statement is inaccurate and unsupported by the record evidence. The Warrick Defendants dispute that the document demonstrates that Warrick was aware that First DataBank was publishing its Direct Prices as WACs. As set forth in General Response No. 3 above, Warrick did not have a WAC price and did not report WACs for the Subject Drugs to any pricing compendia. *See id.* at 155-59. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id.; see also id.* at 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). None of the pricing compendia, First DataBank, Medispan or Red Book, ever reported a WAC for Warrick's drugs in their hard-copy publications. When Warrick realized that First DataBank was publishing Direct Prices for its drugs in 1993, it instructed First DataBank not to do so and First DataBank ceased to publish Direct Prices (and never reported WACs) for Warrick's Subject Drugs in its hard-copy publication. *See* Weintraub Dep. at 153-55; Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Warrick was never aware, during the relevant time, that First DataBank was reporting in its electronic pricing file the Direct Price that Warrick reported for its drugs at launch as a WAC, because Warrick did not subscribe to that service. *See* Weintraub Dep. at 154 & 387. Rather, Warrick only reviewed First DataBank's monthly Price Alerts, which First DataBank specified were its "official" pricing guides. *See id*. at 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product) & 150 (Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents); Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2. Samples of Price Alerts showing no WAC or Direct Price reported for the Warrick Subject Drugs appear in Tab M, to this Response.

In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its alleged undisputed facts. Moreover, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-55.

**Plaintiffs' Reply:**

The admissibility of Exhibit G was addressed by the Court in Mylan. Mylan, 2008 WL 5650859, at footnote 3. Given that this exhibit is being offered for the same purposes here as it was in that instance, namely, to show that Warrick had knowledge that its WAC prices were being published by First Databank in its electronic publications, it is admissible for that purpose. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**15.** Kay Morgan also testified that from time-to-time, FDB would send manufacturers the information FDB was publishing, including WACs, and request that the manufacturer approve and update its information. Deposition of Patricia Kay Morgan dated 1/28/02 (Exhibit H) at 38:5-25, *Mylan*, 2008 WL 5650859 at *17.

Response: Disputed in part.
The Warrick Defendants acknowledge that Kay Morgan testified in 2002 that First DataBank had recently contacted manufacturers to request that they provide price updates. The Warrick Defendants deny that, in the deposition excerpt cited by plaintiffs, Kay Morgan testified that FDB sought updates from manufacturers "from time to time" or earlier than 2002, or that she suggested that FDB requested that the manufacturer "approve" its information. *See* Tab I, Morgan Dep. at 16. Indeed, there is evidence that First DataBank had no such policy of periodically requesting that manufacturers update and/or approve their information. *Id*. at 19-21 (First DataBank had no policy to routinely request updated information from manufacturers); *see also* Weintraub Dep. at 639 (testifying that he did not recall any routine requests from First DataBank for information). Further, notes taken by Kay Morgan, a First DataBank employee, confirm that First DataBank "used [its] own judgment" in setting Warrick's WAC. *See* Tab K, Contested Privilege Dep. of James Breen, at 24–25 (emphasis added).

In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its alleged undisputed facts. Moreover, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-55.

**Plaintiffs' Reply:**

The referenced deposition testimony, in part, taken on January 28, 2002, reads:

> Q: …I'm talking about, now, does First DataBank have a policy or procedure to routinely request updated information for manufacturers?
> A. Yes

The parties agree that that FBD did seek information from manufacturers about their prices so that they could publish the prices that the manufactures wished to be published. The frequency of FDB's requests or whether they were routine is irrelevant and disputed. No further reply is required.

**16.** Warrick refers to its DPs as "Direct Wholesale" indicating that Warrick presents its DPs as its wholesale prices. Warrick Launch Letters dated 12/29/95 and 12/30/95 (Exhibit I), *Mylan*, 2008 WL 5650859 at *17. Warrick knew that its published prices were used for Medicaid reimbursement purposes. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 135:3-25; 137:1-12; Warrick 30(b)(6) (Weintraub) 9/19/06 Dep. (Exhibit C) at 369:7 – 371:23. *Mylan*, 2008 WL 5650859 at *16.

Warrick's Published AWPs and WACs had No Relationship to Actual Prices

Response: Disputed in part.

The Warrick Defendants acknowledge only that a 12/29/95 letter from Warrick to the Massachusetts Medicaid program referred to Warrick's direct price as "Direct Wholesale." The Warrick Defendants deny the characterization that, in doing so, Warrick "presents its DPs as its wholesale prices." The Warrick Defendants deny that Warrick knew "its published prices were used for Medicaid reimbursement purposes" to the extent that the statement does not specify to which "published prices" it refers and to the extent the statement implies that Warrick generally reported to the publishers anything other than AWP and Direct Price at launch.

In addition, as set forth in General Response No. 3 above, Warrick did not have a WAC price and did not report a WAC for the Subject Drugs to any pricing compendia. *See* Weintraub Dep. at 155-59. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id*.; *see also id.* at 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). None of the pricing compendia, First DataBank, Medispan or Red Book, ever reported a WAC for Warrick's drugs in their hard-copy publications. When Warrick realized that First DataBank was publishing Direct Prices for its drugs in 1993, it instructed First DataBank not to do so and First DataBank ceased to publish Direct Prices (and never reported WACs) for Warrick's Subject Drugs in its hard-copy publication. *See id*. at 153-55; Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Warrick was never aware, during the relevant time, that First DataBank was reporting in its electronic pricing file the Direct Prices that Warrick reported for its drugs at launch as WACs, because Warrick did not subscribe to that service. *See* Weintraub Dep. at 154 & 387. Rather, Warrick only reviewed First DataBank's monthly Price Alerts, which First DataBank specified were its "official" pricing guides. *See id*. at 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product) & 150 (Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents); Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2.

As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. In any event, Harvey Weintraub merely testified he was aware that AWP was used in the pharmaceutical industry as a sticker price, a point of reference from which negotiations between a third-party payor and the account it was servicing were

started. *See* Weintraub Dep. at 135. Mr. Weintraub testified that he sent First DataBank launch letters because Warrick's pharmacy customers required that the product be listed in First DataBank, and that Warrick's products needed to be listed in order to be eligible for reimbursement. *See id*. at 352. Mr. Weintraub further testified that he didn't know how the information would be utilized, and he did not specifically intend for it to be used for reimbursement. *See id*. at 566 (testifying that his "intent was to inform [Medicaid programs] of what our direct wholesale price would be going out. How they utilized it, I really don't know.").

In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its alleged undisputed facts. Moreover, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-55.

**Plaintiffs' Reply:**

The parties agree that when Warrick was required to publish WAC in order to be listed in pricing compendia for reimbursement purposes, or directly to state Medicaid offices, it provided its Direct Price. In this respect, whether Warrick believed that what it was providing was the equivalent of WAC or not, the Direct Price was what Warrick gave as its WAC for reimbursement purposes. The exhibits referenced in Plaintiff's Statement No. 16. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**17.** Warrick knows and admits that its reported AWPs were not tethered to the actual prices that anyone pays or to the WAC. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 134:13 – 135:1 (AWP is "a reference point or a sticker price").

Response: Disputed.
The Warrick Defendants acknowledge that Warrick generally reported an AWP at launch that was 10-15% below the AWP for the equivalent brand drug and that, when Warrick entered the market with competitive products, it would set an AWP consistent with the AWPs of competing products. Warrick believes further discovery will show that these practices were consistent with general industry practice. To the extent that plaintiffs intend to imply Warrick continued to report AWPs periodically after launch, Warrick denies the implication. Warrick's AWP at launch would have born some relationship to

its Direct Price or DP at launch, which was invoice price for some transactions at or near the time of launch.

In addition, as set forth in General Response No. 3 above, Warrick did not have a WAC price and did not report a WAC for the Subject Drugs to any pricing compendia. *See* Weintraub Dep. at 155-59. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id.; see also id.* at 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). None of the pricing compendia, First DataBank, Medispan or Red Book, ever reported a WAC for Warrick's drugs in their hard-copy publications. When Warrick realized that First DataBank was publishing Direct Prices for its drugs in 1993, it instructed First DataBank not to do so and First DataBank ceased to publish Direct Prices (and never reported WACs) for Warrick's Subject Drugs in its hard-copy publication. *See id*. at 153-55; Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. Warrick was never aware, during the relevant time, that First DataBank was reporting in its electronic pricing file the Direct Prices that Warrick reported for its drugs at launch as WACs, because Warrick did not subscribe to that service. See Weintraub Dep. at 154 & 387. Rather, Warrick only reviewed First DataBank's monthly Price Alerts, which First DataBank specified were its "official" pricing guides. *See id.* at 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product) & 150 (Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents); Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2. The Warrick Defendants object to plaintiffs' assertion that its "reported AWPs were not tethered to . . . . the WAC." Warrick could not have tethered anything to a price it did not have.

Moreover, NYDOH knew that generic prices decline over time because it received AMP data directly from the Warrick Defendants on a quarterly basis as part of its EPIC program. See, e.g., Tab A, Legislative Changes 2002 (February 6, 2002), NYCO AWP NYDOH 04887. In any event, it is a common industry understanding that price competition for generic drugs is robust and that prices for generic drugs drop over time. *In re Pharm. Indus. Average Wholesale Price Litig*., 230 F.R.D. 61, 94 (D. Mass 2005). Indeed, in the MDL class action, the plaintiffs asserted, and the Court adopted, the principle that competition is so pervasive in the generic market that a Maximum Allowable Cost ("MAC") can be presumed to apply to all generic drugs beginning six months after the first generic launch. *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 87 (D. Mass 2007).

As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL.

**Plaintiffs' Reply:**

Defendants cite NYCO AWP NYDOH 04887 (and gratuitously provide 04888 - 04889) for the proposition that the Department of Health received AMP directly from Warrick on a quarterly basis. This document is inadmissible because it is unauthenticated, unsupported by any testimonial record whatever, unsigned, unattributed, and facially unreliable, entirely apart from the fact that it simply offers no evidence that Warrick provided AMP to NYDOH at any time. In fact, the referenced calculation, by its terms, does not refer to the generic drugs Warrick sells, but only to brand drugs and innovator multi-source drugs, describes in general terms a rebate calculation that is set out in federal regulations, and refers to AMP exclusively in the context of the "baseline AMP," which by its own terms is defined as the AMP for the referenced brand or innovator multisource drugs for the first quarter that drug was in the market. Neither does the document support the general proposition that Plaintiffs' knew that generic drug prices were decreasing over time, apart from the fact that the document does not deal with generic drugs, because the referenced calculation is designed to capture an additional rebate amount only when the prices of the drugs it pertains to increase at a rate that exceeds the consumer price index. If NYDOH knew that prices were generally falling, there would be no rational basis upon which to alter the rebate calculation only to capture price increases. Consequently, this document offers no proof whatever of the proposition for which it is cited, which proposition is irrelevant and disputed.

The parties agree that Warrick set its AWP at product launch and that in spite of admittedly "robust" competition which quickly drove prices down, did not change its AWP. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**18.** At all times relevant to this action, Warrick knew that its generic product line was subject to vigorous competition and that as a result, the actual prices for Warrick's products

would generally decline substantially over time. *See* Warrick Pharmaceuticals Corp. 30(b)(6) (Harvey Weintraub) 9/21/06 Deposition Transcript (Exhibit J) at 753-57 (hereinafter "Warrick 30(b)(6) (Weintraub) 9/21/06 Dep. (Exhibit J)"); Warrick Resp. to Mass. SOF (Exhibit F) at page 9.

Response: Disputed in Part.

The Warrick Defendants acknowledge that Harvey Weintraub testified that the prices for generic drugs generally dropped significantly and rapidly after launch due to price competition. *See* Weintraub Dep. at 89 ("Generic drugs are different in that prices deteriorate very – very rapidly, depending upon the amount of competition for the drug."); 658-59 (testifying that Warrick expected that prices for the inhaler would drop very quickly after launch, but that "[o]ne never knows what the future holds"); 753-57 (testifying that "[a]s a general rule prices for generics fall over time"); 864-65 (testifying that, for the most part, generic products would have falling prices from the time they were launched). However, NYDOH received AMP data directly from the Warrick Defendants on a quarterly basis as part of its EPIC program and, as the reported AMPs for Warrick's Subject Drugs show, while there was a general downward trend over time, the AMPs themselves both increased and decreased at various times over the relevant time period in response to market forces. *See, e.g.*, Tab A, Legislative Changes 2002 (February 6, 2002), NYCO AWP NYDOH 04887; *see also* CD Bates labeled SP-MNYCC0030981, produced by Warrick Defendants on Oct. 27, 2008 (includes Warrick's AMP data). In addition, beginning in January 2002 and continuing every month thereafter, Warrick voluntarily provided New York with a report of its high-low range of prices for the drugs at issue – specifically, Warrick's high and low contract prices for the previous month for each of these drugs, net of described discounts, to each of three main classes of trade: wholesalers, pharmacy chains and generic distributors. These letters showed that prices for Warrick's products varied over time. *See, e.g.*, Tab M, Examples of Monthly Letters from Warrick to NYDOH reporting Warrick's high-low prices.

**Plaintiffs' Reply:**

The Statement as written remains undisputed. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**19.** Warrick sets its AWPs 10-15% below the AWPs of the branded versions of the drugs. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 166:17 – 167:2. When Warrick entered the market and there were already competitive products with AWPs, Warrick would set the AWP for its product "somewhere in the pack" of the competitor AWP values.

Warrick Pharmaceuticals Corp. 30(b)6) (Harvey Weintraub) 9/20/06 Deposition Transcript (Exhibit K) at 527:6 – 528:8.

Response: Undisputed.
As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. CMS officials testified that they could not recall ever having used an AWP as the basis for a FUL. *See* Tab N, Deposition of Gail Sexton, May 20, 2008 ("Sexton Dep.") at 76-77; *see also* Tab O, Deposition of Sue Gaston, March 19, 2008 ("Gaston Dep.") at 456 (discussing the FUL for cefadroxil). The Warrick Defendants acknowledge that Warrick typically set an AWP at launch that was 10-15% below the AWPs of the branded form of the drug and that, when Warrick entered the market with competitive products, it would set an AWP consistent with the AWPs of competing products.

**Plaintiffs' Reply:**

Apart from Defendants' acknowledgment that this Statement is undisputed, the response is irrelevant and disputed. No further reply is required.

**20.** Warrick knows that it does not sell any of its generic drugs at AWP. *See* Warrick 30(b)(6) (Weintraub) 9/21/06 Dep. (Exhibit J) at 760:16 – 761:15 ("I do not remember any such occasion" when Warrick sold a product to a customer at the AWP price); 762:24 – 763:6 ("Q. Warrick knows when it sets its AWP that the price that it charges to the chain is always going to be significantly lower than that price; isn't that true? … A. Generally, yes.").

Response: Disputed in part.
AWP has always been understood to be a reference or benchmark price, not an actual market price, for sales between wholesalers and retailers. It is disingenuous, thus, to assert that AWP would ever have been a price paid to Warrick, a manufacturer. The Warrick Defendants further deny plaintiffs' assertions to the extent that they differ from the testimony cited. Furthermore, as set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL.

**Plaintiffs' Reply:**

The Statement as written remains undisputed. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**21.** After 1995, Warrick made no changes to its AWP. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 167:3-8. Over time chain pharmacies would pay less and less for Warrick products while the AWP stayed the same so that the difference between the pharmacies' market price and Warrick's AWP would grow over time. *See* Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 163:23 – 164:1; Warrick 30(b)(6) (Weintraub) 9/21/06 Dep. (Exhibit J) at 765:11 – 766:10.

Response: Disputed in part.
As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. The Warrick Defendants acknowledge that Warrick generally reported AWPs at launch and that it made no changes to the AWPs for its Subject Drugs after 1995. Warrick acknowledges that selling prices for its generic products generally declined over time as Warrick sought to match the price of its generic competitors. *See* Weintraub Dep. at 753-57. Moreover, NYDOH knew that generic prices decline over time because it received AMP data directly from the Warrick Defendants on a quarterly basis as part of its EPIC program. *See, e.g.*, Tab A, Legislative Changes 2002 (February 6, 2002), NYCO AWP NYDOH 04887. In any event, it is a common industry understanding that price competition for generic drugs is robust and that prices for generic drugs drop over time. *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 94 (D. Mass 2005). Indeed, in the MDL class action, the plaintiffs asserted, and the Court adopted, the principle that competition is so pervasive in the generic market that a Maximum Allowable Cost ("MAC") can be presumed to apply to all generic drugs beginning six months after the first generic launch. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 87 (D. Mass 2007). The Warrick Defendants expect that ongoing discovery will show their practices are within expectations in the generics marketplace.

**Plaintiffs' Reply:**

The parties agree that Warrick generally reported AWPs at launch and that it made no changes to the AWPs for its Subject Drugs after 1995; and that selling prices for its generic products generally declined over time as Warrick sought to match the price of its generic competitors. The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**22.** Warrick's AWPs were not true prices. *Mylan*, 2008 WL 5650859 at *18. Warrick's corporate parents, Schering and Schering-Plough Corporation, understood, condoned and concealed the disparity between Warrick's reported AWPs and the prices generally and currently available in the market. See, Exhibit M, Excerpt from Letter to the Honorable Thomas Bliley, dated August 12, 1999, in which Schering and Schering-Plough Corporation define AWP,

while under investigation by Congress, as "the composite wholesale price charged..." (emphasis added.)

Response: Disputed.
As set forth in General Response No. 2 above, the alleged undisputed material facts relating to AWP are irrelevant and immaterial to this motion, limited as it is to issues relating to the FUL. The Warrick Defendants acknowledge that it understood AWP to be a reference or benchmark, not an actual market price.

In addition, the Warrick Defendants object to plaintiffs' use of the *Mylan* decision, a ruling on summary judgment motions involving different bases of reimbursement, a different state Medicaid program, and entirely different causes of action, that is not yet final, as evidentiary support for its alleged undisputed facts. Moreover, in *Mylan*, the Court concluded, after viewing the proffered evidence in the light most favorable to the moving party, that sufficient disputed material facts existed to preclude summary judgment either for defendants or for plaintiffs. *E.g. Mylan*, 608 F. Supp. 2d at 154-55.

Finally, the Warrick Defendants object to plaintiffs' assertion that Schering and Schering-Plough "understood, condoned and concealed the disparity between Warrick's reported AWPs and the prices generally and currently available in the market" to the extent it implies something is wrong with Warrick's AWPs. Furthermore, the Warrick Defendants object to plaintiffs' reliance on a letter sent by Schering and Schering-Plough, containing no reference to Warrick. As set forth in General Response No. 1, the drugs identified in this paragraph are all generic, Warrick products. The Warrick Defendants acknowledge that Warrick generally reported an AWP at launch that was 10-15% below the AWP of the equivalent brand drug and that, when Warrick entered the market with competitive products, it would set an AWP consistent with the AWPs of competing products. This practice was widely followed in the marketplace, accepted, and certainly not concealed from anyone, including the United States Congress. *See* Tab P, Letter from Raman Kapur to the Honorable Thomas Bliley, dated August 24, 1999 (a similar letter to plaintiffs' Exhibit M importantly written on behalf of Warrick, not Schering).

Moreover, NYDOH knew that generic prices decline over time because it received AMP data directly from the Warrick Defendants on a quarterly basis as part of its EPIC program. *See, e.g.*, Tab A, Legislative Changes 2002 (February 6, 2002), NYCO AWP NYDOH 04887. In any event, it is a common industry understanding that price competition for generic drugs is robust and that prices for generic drugs drop over time. *In re Pharm. Indus. Average Wholesale Price Litig*., 230 F.R.D. 61, 94 (D. Mass 2005). Indeed, in the MDL class action, the plaintiffs asserted, and the Court adopted, the principle that competition is so pervasive in the generic market that a Maximum Allowable Cost ("MAC") can be presumed to apply to all generic drugs beginning six months after the first generic launch. *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 87 (D. Mass 2007).

The Warrick Defendants object to the use of the term "true prices" on the grounds that the truth – or falsity – of a price can only be determined based on a framework of

expectations. Plaintiffs do not define the term "true prices," nor do they define the framework within which the alleged truthfulness of Warrick's AWPs is being judged. On these grounds, plaintiffs' assertion that "Warrick's AWPs were not true prices" can be neither admitted or denied.

**Plaintiffs' Reply:**

Defendants' Exhibit P supports Plaintiff's Statement, and does not refute it. The fact that a relatively new, relatively small unit of Schering-Plough (Warrick) was providing a description of it use of the term "AWP" to Congress which so completely and obviously conflicted with the definition provided by its corporate parents – giants in the pharmaceutical industry for many years – shows that these corporate parents both understood and condoned Warrick's departure from any reasonable use of the term, and that they sought to give Warrick cover by perpetuating in the public eye, and in the eyes of Congress, the notion that AWP was actually a real price, "the composite wholesale price charged."

The remainder of Defendants' response is irrelevant and disputed. No further reply is required.

**23.** Warrick admits that it reported a Direct Price to the pricing compendia at product launch. *See* Warrick Resp. to Mass. SOF (Exhibit F) at page 11-12.

Response: Undisputed.
The Warrick Defendants acknowledge that at the launch of a product, Warrick generally set a direct price. *See* Weintraub Dep. at 153-54; *see also id*. at 353 (direct price was the "going-out price" that Warrick intended to get if it could) & 566 (direct price was the initial "going-out price" expected for the wholesale class of trade). After launch, Warrick did not maintain a uniform direct price that was the same for each customer. *See id*. at 153. For that reason, in a letter dated October 12, 1993, Harvey Weintraub asked First DataBank to "[p]lease delete direct price listings from your publication or database." *Id*.; *see also* Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993.

**Plaintiffs' Reply:**

Apart from Defendants' acknowledgement that the Statement is undisputed, Defendants' response is irrelevant and disputed. No further reply is required.

**24.** Schering/Warrick calculated and reported the average manufacturer's price ("AMP") for all its products on a quarterly basis as required by the federal rebate statute. *Mylan*, 2008 WL 5650859 at *30.

Response: Undisputed.
The Warrick Defendants acknowledge that Warrick calculated and reported AMPs for all of its products on a quarterly basis as required by the federal rebate statute and to NYDOH as part of its EPIC program. As set forth in General Response No. 1, the drugs identified in this paragraph are all generic, Warrick products. Accordingly, the Warrick Defendants dispute plaintiffs' alleged material fact to the extent it purports to relate to Schering.

**Plaintiffs' Reply:**

Apart from Defendants' acknowledgement that the Statement is undisputed, Defendants' response is irrelevant and disputed. No further reply is required.

**Defendants' Additional Statements of Undisputed Material Facts**

**1.** CMS officials would decline to set a FUL when the FUL was equal to an AWP because States' "regular reimbursement methodology would be a percentage off of AWP," such that setting a FUL that was equal to AWP "would kind of counter what the states were doing with their other reimbursement methodology." Tab O, Gaston Dep. at 456 (discussing the FUL for cefadroxil); *see also* Tab N, Sexton Dep. at 76-77 (stating that she could not recall ever having set a FUL based on an AWP).

**Plaintiff's Response:**

Plaintiffs dispute Statement No. 1 to the extent that it implies (by using "would decline") that in an alternative circumstance wherein, as Plaintiffs postulate in their

motion, Defendants' reported AWP prices were real and actually a composite of generally and currently available wholesale prices to the provider classes of trade, CMS officials would decline to use them according to the dictates of the FUL regulation, which speaks in terms of the lowest published price, without regard to whether that price is an AWP, a WAC, or some other published price. Plaintiffs do not dispute that Statement No. 1 reproduces in part the testimony of Sue Gaston as cited. Nevertheless, Gaston's testimony about what she did to set FUL in the face of an entirely inflated and fraudulent array of published prices, without the knowledge and understanding that this was what she was actually facing at the time, is irrelevant to any matter at issue on this motion, and its implications are entirely disputed. *See* Declaration of Susan E. Gaston, dated June 15, 2009 ("Gaston Dec.") at ¶ 7, ¶ 10, ¶ 12 (Exhibit C to the Affidavit of Joanne M. Cicala in Opposition to Defendants' Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims ("Cicala Aff.") [Docket No. 6144, Sub-docket No. 97]).

**2.** Ms. Gaston testified that CMS "wouldn't have used AWP" when establishing FULs because "[s]etting a FUL using the AWP wouldn't achieve the cost savings." Tab O, Gaston Dep. at 458-59; *see also* Tab N, Sexton Dep. at 58–59 ("[I]f the federal upper limit, once it was calculated, was higher than the AWP price for the majority of the AWP prices, then we would generally not set a FUL on those drug ingredients, because the AWP—well, a couple years ago the average AWP on a national basis was I think AWP minus 12 percent for drug reimbursement, estimated acquisition costs for drug reimbursement for a drug that did not have a federal upper limit.").

**Plaintiffs' Response:**

Plaintiffs dispute Statement No. 2 to the extent that it implies (by using "wouldn't have used AWP") that in an alternative circumstance wherein, as Plaintiffs postulate in their motion, Defendants' reported AWP prices were real and actually a composite of generally and currently available wholesale prices to the provider classes of trade, CMS

officials would decline to use them according to the dictates of the FUL regulation, which speaks in terms of the lowest published price, without regard to whether that price is an AWP, a WAC, or some other published price. Plaintiffs do not dispute that Statement No. 2 reproduces in part the testimony of Sue Gaston as cited. Nevertheless, Gaston's testimony about what she did to set FUL, or to decline to do so in the face of an entirely inflated and fraudulent array of published prices, without the knowledge and understanding that this was what she was actually facing at the time, is irrelevant to any matter at issue on this motion, and its implications are entirely disputed. *See* Declaration of Susan E. Gaston, dated June 15, 2009 ("Gaston Dec.") at ¶ 7, ¶ 10, ¶ 12 (Exhibit C to the Affidavit of Joanne M. Cicala in Opposition to Defendants' Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims ("Cicala Aff.") [Docket No. 6144, Sub-docket No. 97]).

**3.** Warrick understood Wholesale Acquisition Cost, or WAC, to be "[a]n undiscounted invoice price . . . [to] the wholesaler." Weintraub Dep. at 156.

**Plaintiffs' Response:**

Plaintiffs' dispute Statement No. 3. Warrick was founded and operated on a day-to-day basis during the relevant period by Harvey Weintraub, who had been in the pharmaceutical manufacturing industry by the time of Warrick's founding for over forty years. He retired as an executive of Schering knowing that his next assignment, as a Schering-Plough "consultant," would be to get Warrick off the ground. *See*, Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 49:12-22; 76:11-77:20; and 85:24-86:5. During that time, WAC has been known in the industry as the cost to wholesalers to acquire pharmaceutical products from manufacturers, as opposed to the list or invoice

price. This has been established to be the case by this Court. *See generally*, *Mass. v. Mylan, et al.*, 608 F.Supp.2d 127, at 140-141. Weintraub's self-serving testimony to the side, it is inconceivable that he would have worked for so long in the industry without understanding the longstanding meaning of WAC.

**4.** Warrick did not have a WAC. See Weintraub Dep. at 156-57. Warrick separately negotiated with its wholesaler and chain pharmacy customers and typically invoice prices "were different for each customer." *Id.; see also id*. at 528-29 (Warrick would have a whole range of different prices, and the prices would be different for different customers and according to the position of the competition). Warrick did not use the term WAC in its business on a routine basis. *See id. at 156-57*.

**Plaintiffs' Response:**

Plaintiff's dispute Statement No. 4. Warrick did have a WAC as that term is defined by the Court:

> "The defendants' interpretation of WAC would give the defendants a virtual blank check because they could simply denominate a price as a WAC even if it was not the real price charged to most wholesalers, and the Commonwealth would then compensate on the basis of that "list price." Such a result is absurd and fortifies the conclusion that, even were deference not due to the agency, **WAC means 'the price that wholesalers actually paid to acquire the drug.'"**

*Mass. v. Mylan, et al.*, 608 F. Supp.2d 127, at 144 (emphasis added).

Whether Warrick chose to calculate or estimate it in good faith is another matter entirely. Plaintiffs do not dispute the assertion that Warrick had different prices for different customers, but contend that this is both extremely common in the industry and entirely irrelevant. Plaintiffs dispute the assertion that Warrick did not use the term WAC in its business on a routine basis. Weintraub testifies that Warrick did have occasion to use the term in the ordinary course in order to deal with wholesalers, such as

Cardinal, who "wanted everything as WAC for their purposes to make sure we were on the same page." *See*, Warrick 30(b)(6) (Weintraub) 9/18/06 Dep. (Exhibit B) at 157:19-158:5. It is undisputed that Cardinal is one of the three national full-line drug wholesalers doing business with Warrick, and that Cardinal is one of Warrick's key accounts. In view of Weintraub's admitted familiarity with the term WAC, and his use of it exclusively with Cardinal, at least, Warrick cannot reasonably contend that "WAC" was not in regular or routine use in its everyday business.

**5.** Warrick did not regularly publish a list of prices. *See* Weintraub Dep. at 157. Warrick did not report a WAC to pricing compendia for the Subject Drugs. *Id*. at 155-59.

**Plaintiffs' Response:**

Plaintiffs dispute Statement No. 5. Warrick has admitted that it regularly on the launch of a product, published a list containing AWP and Direct Price to the pricing compendia, as well as directly to the state Medicaid agencies. Warrick has also admitted that it regularly published such lists of prices (AWPs, Direct Prices, and on at least one occasion, WAC) to pricing compendia and state Medicaid officials on request. To the extent only that Statement No. 5 suggests that Warrick did not periodically publish a complete list of its products containing AWP, WAC, or other pricing information to the pricing compendia, Plaintiffs have no cause for dispute, but contend that such an interpretation of the Statement renders it irrelevant to any matter at issue on this motion.

**6.** At the launch of a product, Warrick generally set a direct price. *See* Weintraub Dep. at 153-54, 353 (direct price was the "going-out price" that Warrick intended to get if it could), 566 (direct price was the initial "going-out price" expected for the wholesale class of trade).

**Plaintiffs' Response:**

Plaintiffs do not dispute the first sentence of Statement No. 6. The remainder of Statement No. 6 is disputed. Warrick did not expect to obtain the launch direct price. Warrick price-protected its customers at launch, and actually expected significant price erosion, even in the first thirty days, Weintraub's referenced testimony, particularly regarding the launch of the inhaler, notwithstanding. *See*, Exhibit H.

**7.** Warrick typically sent letters at the launch of a product to customers, pricing compendia, and state Medicaid agencies, including New York, providing notice of the product's AWP and NDC number, and occasionally its direct price at launch. *See, e.g.*, Weintraub Dep. at 639 (testifying that Warrick's procedure when launching a new product was to notify First DataBank of the AWP and NDC numbers); Tab D, Weintraub Letter from Harvey Weintraub to Beth Rader and Ed Edlestein dated Sept. 3, 1993 (announcing availability of 25 x 3 ml albuterol sulfate inhalation solution 0.083%, 59930-1500-08 and reporting AWP and direct price at launch); Tab E, Letter from Harvey J. Weintraub to Beth Rader dated Dec. 29, 1995 (announcing availability of albuterol USP inhalation aerosol (59930-1560-1) and refill (59930-1560-2) and reporting AWP); Tab F, Letter from Phyllis T. Sinoradzki, M.A.E. to Arnold Shapiro dated Dec. 30, 1995 (announcing availability of albuterol USP inhalation aerosol (59930-1560-1) and refill (59930-1560-2) and reporting AWP and direct price at launch for same).

**Plaintiffs' Response:**

Undisputed.

**8.** Warrick sells its products almost entirely to wholesalers, large chain pharmacies, and generic distributors and, in so doing, competes based on price, quality, and reliability of supply. *See* Weintraub Dep. at 104-06, 113-14, 121, 125, 141-142. Because of the price-competitive nature of the generic industry, Warrick's principal competitive tool was to match the price of its generic competitors in order to obtain and maintain business. *See id.*

**Plaintiffs' Response:**

Assuming that the phrase, "competes on price" may be interpreted as including the proposition that Warrick created, maintained, and relied in some measure upon the spread between its reported prices and the actual prices providers paid for Warrick products in order to incentivize them to purchase Warrick products, Plaintiffs do not

dispute the Statement. Plaintiffs do not dispute that Warrick sold primarily to the classes of trade listed in the Statement, or that Warrick attempted to compete on the various bases listed. Plaintiffs do dispute the Statement's assertion that price matching was Warrick's "principal competitive tool," or that the cited testimony supports such a proposition.

**9.** Generic manufacturers compete vigorously to provide the generic version of a drug stocked by a particular pharmacy or pharmacy chain. *See* Weintraub Dep. at 89 (generic drug prices deteriorate very rapidly depending on the amount of competition for a drug). As a result of that competition, Warrick's prices generally declined substantially over time, as do the prices for most generic drugs. *See, e.g.*, Weintraub Dep. at 753-57; *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 94 (D. Mass 2005). Indeed, in the MDL class action, the plaintiffs asserted, and the Court adopted, the principle that competition is so pervasive in the generic market that a Maximum Allowable Cost ("MAC") can be presumed to apply to all generic drugs beginning six months after the first generic launch. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 87 (D. Mass 2007).

**Plaintiffs' Response:**

Plaintiffs do not dispute the Statement as written. Plaintiffs do dispute the implication that the Court's presumption, made in the class case, is in anywise relevant or binding upon the Court in this matter.

**10.** In October 1993, Warrick directed First DataBank not to publish a Direct Price for its products. Warrick knew that it did not have a direct price that was the same for every customer, so there was no point in listing a direct price. *See* Weintraub Dep. at 153; *see also* Tab G, Letter from Harvey J. Weintraub to Beth Rader and Ed Edlestein dated Oct. 12, 1993. As far as Warrick was aware, FDB stopped reporting a direct price in its hard-copy publication after Mr. Weintraub asked them to remove it. *See* Weintraub Dep. at 153-55.

**Plaintiffs' Response:**

Plaintiffs do not dispute the first sentence of Statement No. 10. The remainder of the Statement is disputed. *See,* Plaintiff's Reply to Defendants' Response to Statement No. 1, *supra.*

**11.** First DataBank did not publish a WAC for Warrick's products in its hard-copy publication, the monthly Price Alerts, which First DataBank specified were its "official" pricing guides, and Warrick was not aware that First DataBank was publishing the Direct Prices Warrick reported to First DataBank at launch for its products in its electronic databases as WACs. *See* Weintraub Dep. at 154, 387, 581-82; Tab C, A Proposal for the Exclusive Sponsorship of Price Alert, June 1991, at 2. While Warrick subscribed to First DataBank's monthly Price Alert, no WAC appeared in this hard-copy publication for any Warrick product. Tab Q, First DataBank Price Alert dated Dec. 15, 1997, First DataBank Price Alert dated Nov. 15, 1999, First DataBank Price Alert dated Nov. 15, 2001, and First DataBank Price Alert dated Nov. 15, 2003; Tab B, Weintraub Dep. at 153-155, 444-45 (Mr. Weintraub testified that he is familiar only with the booklet Price Alert and not with First DataBank's electronic product). Warrick did not have access to the electronic version of First DataBank's publication used by states and their fiscal agents. *See id.* at 150. None of the other written pricing compendia published WACs for Warrick's products.

**Plaintiffs' Response:**

Plaintiffs dispute only the penultimate sentence of Statement No. 11. Warrick admits that it had access to all of the resources of Schering as a unit of Schering-Plough, and that its decision not to use any particular part of them in the prosecution of Warrick's business was deliberate. *See*, Warrick 30(b)(6) (Weintraub) 9/21/06 Dep. (Exhibit B) at 749:21-750:22. It is undisputed that Schering, and Warrick had it chosen to exercise it, had recourse to the electronic version of the FDB National Drug Data File. *See,* Exhibit G. And finally, Janice Brennan, the Schering employee whose job it was to interface with Medicaid agencies and pricing services, clearly did so on behalf of Warrick, and indisputably had access to the electronic NDDF files showing that Warrick's WACs were being published electronically in spite of the fact that they were not published in the paper publication. *See,* Warrick 30(b)(6) (Weintraub) 9/20/06 Dep. (Exhibit B) at 583:5-13 and Exhibit G. The remainder of Statement No. 11 is undisputed.

**12.** Since as early as 1991, NYDOH received AMP data directly from the Warrick Defendants as part of its EPIC program, which helps seniors in the State of New York pay for prescription drugs. *See, e.g.*, Tab A, Legislative Changes 2002 (February 6, 2002), NYCO AWP NYDOH 04887.

**Plaintiffs' Response:**

Undisputed.

**13.** New York also had access to AMPs since 1991 through the URAs it received on a quarterly basis as part of the federal Medicaid Rebate Program. *See* 42 U.S.C. §§ 1396r-8(a)(1), (b)(1). URAs are derived from AMPs by formulae that are set forth in the federal statute, see 42 U.S.C. § 1396r-8(c)(1), and (3), and in the Rebate Agreement with every State. *See* Medicaid Program: Drug Rebate Agreement, 56 Fed. Reg. 7049; *see also* Tab R, 1991 Rebate Agreement. For most generic drugs, URA is 11% of AMP; for innovator generic drugs and brand drugs, URA is no less than 15 % of AMP. *Id.* In every quarter since 1991, CMS has reported to each State the Unit Rebate Amount or "URA" for each product covered by Medicaid. *See* 42 U.S.C. §§ 1396r-8(a), (b). In addition, since 1995, New York has had access to actual acquisition cost information in its claims data in the form of 340B prices, which are generally defined as AMP minus URA. Moreover, since 2006, New York has received AMPs directly from CMS under the Deficit Reduction Act of 2005. See Medicaid Program, Prescription Drugs, 71 Fed. Reg. 77174, *77174-77176 (Dec. 22, 2006).

**Plaintiffs' Response:**

Plaintiffs dispute Statement No. 13 to the extent that it implies that AMP information was available to the Medicaid program in New York for any purpose other than calculating and collecting Medicaid rebates. The use of such information for the purpose of establishing or otherwise affecting the reimbursement methodology or amounts was prevented by the confidentiality provisions of the federal rebate agreement to which New York was a party, as well as by statutory and regulatory confidentiality provision pertaining to AMP and related manufacturer information, as well as by CMS/HCFA policy prohibiting the use of AMP and related information for reimbursement purposes. Otherwise, the Statement is undisputed.

**14.** Beginning in January 2002 and continuing every month thereafter, Warrick voluntarily provided New York with a report of its high-low range of prices for the drugs at issue – specifically, Warrick's high and low contract prices for the previous month for each of these drugs, net of described discounts, to each of three main classes of trade:

wholesalers, pharmacy chains and generic distributors. *See, e.g.*, Tab M, Examples of Monthly Letters from Warrick to NYDOH Reporting Warrick's High-Low Prices.

**Plaintiffs' Response:**

Plaintiffs dispute Statement No. 14, and submit that no evidence of the provision of such prices has been offered in support of the Statement. The referenced letters were produced by Schering and have not been authenticated or corroborated by any testimony, and offer no indication on their face that they have ever been anywhere near New York. Furthermore, the letters themselves only purport to transmit information which is not a part of the record at all.

**15.** In addition to the errors cited in Defendants' Joint Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts Related to Federal Upper Limits and Applicable to All Thirteen FUL Defendants, plaintiffs' expert Harris Devor testified that he included "free goods" to charities in his calculations of "true" AWPs and WACs for Warrick drugs. *See* Tab S, Deposition of Harris Devor, Dec. 9, 2008 & March 11, 2009 ("Devor Dep."), at 124-25 (testifying that he subtracted nearly $3 million of free goods for charitable purposes from his calculation of a "Devor WAC" for Warrick).

**Plaintiffs' Response:**

Plaintiffs dispute Statement No. 15, and submit that no evidence is offered for the proposition that any transaction included by Mr. Devor as a "free good" was in fact given to charity. Devor could not, and did not testify that the goods were "for charitable purposes," as alleged, because no information regarding the purpose of the transactions marked as "free goods" was provided by Defendants in the context of the transactional data.

**16.** When asked why he included "free goods to customers" in his calculations, Mr. Devor testified:

[T]here is [sic] a whole lot of classes of trade. I don't have them memorized, no. I have no idea. Alls I can go by is what it says here. It says

free goods customers. If it turns -- I mean, it could very well be charitable but I have no -- I have no knowledge of that, I guess is what I am saying.

*See* Devor Dep. at 126.

**Plaintiffs' Response:**

Undisputed.

**17.** When asked whether he tried to contact anyone at Warrick to determine the meaning of the "free goods" class of trade, Mr. Devor testified: "I did not. I mean – no, I did not – did I attempt to speak with Warrick? The answer is no." *See* Devor Dep. at 128-29.

**Plaintiffs' Response:**

Undisputed.

**18.** In addition, Mr. Devor testified that, when deducting chargebacks from his calculations, he treated negative numbers as positive numbers in calculating chargeback amounts. *See* Devor Dep. at 943-44.

**Plaintiffs' Response:**

Undisputed.

**19.** Mr. Devor "assumed" that the "predominant" type of chargebacks in a manufacturer's data – positive or negative – was representative of all chargebacks in that manufacturer's data and then altered the non-predominant numbers accordingly. *See* Devor Dep. at 951-52.

**Plaintiffs' Response:**

Undisputed.

**20.** Thus, for example, Mr. Devor confirmed that he changed negative charge-back information from Warrick to positive charge-back information without considering whether the negative charge-back numbers for Warrick might represent an overpayment by Warrick that was credited back by the wholesaler. *See* Devor Dep. at 953-55.

**Plaintiffs' Response:**

Plaintiffs dispute Statement 20. Devor's testimony supports the proposition that, in accordance with appropriate professional judgment, he assumed that when the transaction

data showed that chargebacks were being carried predominantly as negative or positive numbers, it made sense to treat them consistently. Devor did not assume that when the data used predominantly negative numbers to express chargebacks it meant that the majority of chargeback transactions were due to overpayments being recouped. This would have been extraordinary.

**21.** Mr. Devor testified that he did not check with Warrick, or any other manufacturer, to see why certain chargebacks might be positive and others might be negative. *See* Devor Dep. at 910, 913-14, 917 ("no, nobody talked to Warrick").

**Plaintiffs' Response:**

Undisputed.

Dated: June 30, 2009

Respectfully submitted,

**City of New York and New York Counties in MDL 1456 except Nassau and Orange by**

**KIRBY McINERNEY, LLP**
825 Third Avenue
New York, New York 10022
(212) 371-6600

/s/ Joanne M. Cicala
By: Joanne M. Cicala
James P. Carroll Jr.
Jocelyn R. Normand
Kathryn B. Allen

Ross B. Brooks, Esq.
MILBERG LLP
One Pennsylvania Plaza
New York, NY 10119
(212) 594-5300

*Special Counsel for the County of Nassau*

Theresa A. Vitello, Esq.
LEVY PHILLIPS &
KONIGSBERG, LLP
800 Third Avenue
New York, NY 10022
(212) 605-6205
*Counsel for the County of Orange*

**CERTIFICATE OF SERVICE**

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' REPLY TO SCHERING CORPORATION'S, SCHERING-PLOUGH CORPORATION'S, AND WARRICK PHARMACEUTICALS CORPORATION'S RESPONSE TO PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF "UNDISPUTED" MATERIAL FACTS AS TO SCHERING CORPORATION, SCHERING-PLOUGH CORPORATION, AND WARRICK PHARMACEUTICALS CORPORATION AND STATEMENT OF ADDITIONAL UNDISPUTED MATERIAL FACTS, to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: June 30, 2009

/s/
James P. Carroll, Jr.
Kirby McInerney LLP
825 Third Avenue, 16th Floor
New York, NY 10022
(212) 371-6600